

Publication

Community access to rectal artesunate for malaria (CARAMAL): a large-scale observational implementation study in the Democratic Republic of the Congo, Nigeria and Uganda

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The key to reducing malaria deaths in highly endemic areas is prompt access to quality case management. Given that many severe cases occur at peripheral level, rectal artesunate (RAS) in the form of suppositories was developed in the 1990s, allowing for rapid initiation of life-saving antimalarial treatment before referral to a health facility with full case management capabilities. One randomized controlled trial published in 2009 showed a protective effect of RAS pre-referral treatment against overall mortality of 26%, but with significant differences according to study sites and length of referral. Two important issues remained unaddressed: (1) whether the mortality impact of RAS observed under controlled trial conditions could be replicated under real-world circumstances; and (2) clear operational guidance for the wide-scale implementation of RAS, including essential health system determinants for optimal impact. From 2018 to 2020, the Community Access to Rectal Artesunate for Malaria (CARAMAL) project was conducted as a large-scale observational implementation study in the Democratic Republic of the Congo (DRC), Nigeria, and Uganda (registered on ClinicalTrials.gov as NCT03568344). CARAMAL aimed to provide high-quality field evidence on the two issues above, in three remote settings with high malaria endemicity. A number of complementary study components were implemented. The core of the CARAMAL study was the Patient Surveillance System (PSS), which allowed tracking of cases of severe febrile illness from first contact at the periphery to a referral health facility, and then on to a Day 28 visit at the home of the patient. Community and provider cross-sectional surveys complemented the PSS. Here we describe in some detail RAS implementation, as well as the key CARAMAL study components and basic implementation experience. This manuscript does not intend to present key study results, but provides an extensive reference document for the companion papers describing the impact, referral process, post-referral treatment and costing of the RAS intervention.

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